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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,927	12/16/2005	Lone Andersen	05198-P0012A	6616
24126	7590	07/27/2010		
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STAMFORD, CT 06905-5619				
EXAMINER				
LATHAM, SAEEDA MONEE				
ART UNIT		PAPER NUMBER		
1782				
MAIL DATE		DELIVERY MODE		
07/27/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,927

Applicant(s)

ANDERSEN ET AL.

Examiner

Saeeda Latham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53, 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment to the claims filed on 5/10/2010 has been entered. Claims 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53, 56 are currently pending in this application. The previous rejection under the second paragraph of 35 U.S.C. 112 is withdrawn in view of applicant's amended claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 2, 6, 8, 9, 14-18, 20-26, 28-31, 33-39, 49, 50, 52, 53, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al., USPN 5672367 in view of Ohara et al., USPN 5508378.**

3. Claim 1, 2, 6, 8, 9, 28, 29, 50, 52, 53, 56 relate to a chewing gum and method. Grijpma teaches a biodegradable chewing gum comprising at least one biodegradable polymer (abstract). In the absence of the teaching that the chewing gum is free of non-biodegradable polymers, it is understood that the claim limitation is met. Grijpma further teaches the method for the polymerization in Examples 1 and 3. The various chewing gum ingredients are added to a mixer, and then brought into desired form (column 3, lines 6-10). Grijpma

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teaches softeners at 0.5 to 15% in the chewing gum such as glycerin, lecithin and combinations (column 2, lines 46-50). Grijpma further teaches emulsifiers such as fatty acid monoglycerides, diglycerides and triglycerides (column 2, lines 30-32).

4. Grijpma does not explicitly teach less than 12% softeners. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected 0.5 to less than 12% because of the overlapping range of Grijpma.

5. Grijpma does not teach the biodegradable polymer having a molecular weight or adjusting the molecular weight. Ohara teaches the method for producing a polylactic acid that is biologically safe, having a high molecular weight of 200,000 to 500,000, and is freed from coloration and containing substantially no decomposition products (Column 1, lines 14; Column 2, lines 22-24). The presences of lactides and decomposition products cause undesirable adherence to nozzles during molding and deterioration of polymer formability and thermal stability (Column 1, lines 54-61). Ohara further teaches the polylactic acid can be further progressed and unreacted lactide can be reacted further, the reaction can be terminated to yield an average high molecular weight polymer (column 2, lines 5-7, examples 1-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the teachings of Ohara to make the high average molecular weight polylactic acid that contains substantially no decomposition products to produce Grijpma's biodegradable gum using a good quality formable polymer.

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6. Neither Grijpma nor Ohara explicitly teach a number average molecular weight or polydispersity. It would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures to yield the desired number average molecular weight and polydispersity.
7. Claims 14-18, 20 relate to flavoring agents. Grijpma teaches the chewing gum can further contain flavoring agents such as citrus oil [considered water insoluble], fruit extracts [considered water soluble] at 0.1% and 10% by weight (column 2, lines 64-67).
8. Claim 21-26 relates to sweeteners. Grijpma teaches the addition of sweeteners preferably 5 to 95% (column 2, lines 42-45). The sweeteners include sorbitol, cane sugar syrup, sucrose, dextrose and aspartame, acesulfame and saccharide either alone or in combination (column 2, lines 50-62).
9. Grijpma does not teach less than 1% of high intensity sweeteners. It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected less than 1% of high intensity sweeteners in combination with other non-high intensity sweeteners as taught by Grijpma to achieve the desired sweetness in the chewing gum product.
10. Claims 30 and 31 relate to active ingredients. Grijpma teaches the gum containing fillers such as calcium carbonate and antioxidants (column 2, lines 33-39). Grijpma further teaches the presence of medicinal and/or mouth conditioning components (column 3, lines 4-5).

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11. Claims 33-36 relate to the polymerization of the biodegradable polymer.

Grijpma teaches a copolymer of l-lactide and d-lactide and addition of ε-caprolactone by ring-opening polymerization (examples 1 and 3). It is preferred that the gum base is based on a copolymer of lactide and one or more cyclic esters such as trimethylene carbonate with at least one of the polymers containing lactide (column 1, lines 57-65).

12. Claim 33 is considered a product-by-process claim. The cited prior art teaches all of the positively recited composition of the claimed product. The determination of patentability is based upon the composition itself. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

13. Claims 37 and 38 relate to filler. Grijpma teaches the addition of fillers in the amount of 10 to 15% (column 2, lines 35-36).

14. Claim 39 relates to coloring agents. Grijpma teaches adding colouring agents (column 3, line 14).

15. Claim 49 relates to the chewing gum. Grijpma teaches the copolymer as gum base for making chewing gum with 35%, 58%, and 62% gum base (example 2). Grijpma teaches plasticizers or softeners added at 0.5 to 15% in the chewing gum such as glycerin, lecithin and combinations (column 2, lines 46-50). Grijpma teaches fillers in the amount of 10 to 15% (column 2, lines 35-36). Grijpma

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teaches the chewing gum can further contain flavoring agents such as citrus oil, fruit extracts at 0.1% and 10% by weight (column 2, lines 64-67).

16. Claims 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al., USPN 5672367 in view of Ohara et al., USPN 5508378, in further view of Zyck et al., USPGpub 2001/0021373.

17. Grijpma teaches a biodegradable chewing gum comprising at least one biodegradable polymer (abstract). Grijpma further teaches the processing the gum where it is brought to desired form by extruding or pelleting (column 3, lines 10-11). Grijpma is further modified by incorporating the teachings of Ohara to make the high average molecular weight polylactic acid that contains substantially no decomposition products to produce biodegradable gum using a good quality formable polymer of Grijpma

18. Neither Grijpma nor Ohara teach coating chewing gum. Zyck teaches a coated chewing gum product where the coating is sugarless and may comprise xylitol, sorbitol, gelatin, flavors, and other common conventional coating agents [0056]. Zyck further teaches the coating can be dried to form a hard surface [0062] and also applying a plurality of liquid layers and drying is used in "soft" panning [0069]. Zyck further teaches using a gum mass that is formed into pellets, which is used as the core for the coated product using conventional panning techniques [0055]. It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized conventional panning techniques to coat gum taught by Zyck and further processed the gum pellets of Grijpma to produce a coated chewing gum.

19. **Claims 1, 2, 6, 8, 9, 14-26, 28-31, 33, 36-39, 49, 50, 52, 53, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al., WO 00/19837.**

20. Claims 1, 2, 6, 8, 9, 28, 29, 50, 52, 53, 56 relate to a chewing gum and method. Li teaches chewing gum that is environmentally friendly containing the chewing gum base comprises poly (D, L-lactic acid) copolymers (abstract, Page 2 line 10). Li teaches melting the gum base and adding other components to a mixer (Page 13, lines 7-14). Li teaches the advantage is to provide a chewing gum that is biodegradable (Page 4, lines 1-12). In the absence of the teaching that the chewing gum is free of non-biodegradable polymers, it is understood that the claim limitation is met. Li teaches several embodiments wherein the poly (D, L-lactic acid) has a molecular weight range of approximately 2000 to about 2000000 g/mol and 10000 to about 500,000 g/mol (Page 2, lines 27, 30). The softener such as lecithin is typically from about 0.5% to about 25% by weight of the chewing gum (Page 11, lines 25-30).

21. Li does not teach the biodegradable polymer of at least 105000 g/mol or higher (Mn) or polydispersity. It would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures to yield the poly (D, L-lactic acid) of Li with the desired molecular weight and polydispersity using the ranges taught.

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22. Li does not explicitly teach less than 12% softeners. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected 0.5 to less than 12% because of the overlapping range of Li.

23. Claims 14-20 relate to flavoring agents. Li teaches flavoring agents that are water soluble and water insoluble (Page 6, lines 27-28). Flavoring agents such as essential oils, synthetic flavors, heat-modified amino acids at a range of 0.5 to about 3 weight percent of the gum (Page 12, lines 21-24, Page 10, line 8).

24. Claims 21-26 relate to sweeteners. Li teaches sweeteners often are used as bulking agents that comprise about 5 to about 90% (Page 11, lines 21-23). High intensity sweeteners may be included such as sucralose, aspartame, acesulfame, alitame and dihydrochalcones in a range of 0.02 to 0.10 weight percent (Page 12, lines 14-20).

25. Li does not teach less than 18%. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected about 0.5% up to less than 18% because of the overlapping range.

26. Claims 30 and 31 relate to active ingredients. Li teaches antioxidants may be used in the gum base such as vitamin C (Page 7, lines 21-25). Also Li teaches the addition of magnesium and calcium carbonate, magnesium and aluminum silicate (Page 9, lines 15-16). Further Li teaches pharmaceutical agents are optional ingredients (Page 12, line 31).

27. Claims 33 and 36 relates to the biodegradable polymer. Li teaches the chewing gum base comprises poly (D, L-lactic acid) copolymers (abstract).

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28. Claims 37 and 38 relates to filler. Li teaches filler is used to modify the texture of the gum (Page 9, line 13).

29. Claim 39 relates to coloring agents. Li teaches colorants (Page 10, line 5).

30. Claim 49 relates the chewing gum. Li teaches chewing gum that is environmentally friendly containing the chewing gum base comprises poly (D, L-lactic acid) copolymers (abstract, Page 2 line 10). Flavoring agents such as essential oils, synthetic flavors at a range of 0.5 to about 3 weight percent of the gum (Page 12, lines 21-24).

31. Li does not explicitly teach the amount of plasticizer. Li teaches plasticizers vary the firmness of the gum base, gum can be softened by plasticizers, and the plasticizer can be used as softeners (Page 8, lines 19, 26; Page 5, line 9). Li teaches that softener is typically from about 0.5% to about 25% by weight of the chewing gum (Page 11, lines 25-30). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the amount of softener as the plasticizer taught by Li to produce a chewing gum with a suitable amount of firmness.

32. Claims 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al., WO 00/19837 in view of Zyck et al., USPGpub 2001/0021373.

33. Claim 40 relates to coating chewing gum. Li teaches chewing gum that is environmentally friendly containing the chewing gum base comprises poly (D, L-lactic acid) copolymers (abstract, Page 2 line 10). Li further teaches the gum

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mass is shaped into a desired form such as cutting into sticks, extruding into chunk, or casting into pellets (Page 13, lines 5-6).

34. Li does not teach coating chewing gum. Zyck teaches a coated chewing gum product where the coating is sugarless and may comprise xylitol, sorbitol, gelatin, flavors, and other common conventional coating agents [0056]. Zyck further teaches the coating can be dried to form a hard surface [0062] and also applying a plurality of liquid layers and drying is used in "soft" panning [0069]. Zyck further teaches using gum mass that is formed into pellets that are used as the core for the coated product using conventional panning techniques [0055]. It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized conventional panning techniques to coat gum as taught by Zyck and the gum pellets/sticks of Li to produce a coated chewing gum.

Response to Arguments

35. Applicant's arguments filed 5/10/2010 have been fully considered but they are not persuasive. Applicant argues that Ohara is not relevant to the art of chewing gum (see Remarks Page 3).

36. In response to applicant's argument, both Grijpma and Ohara teach biodegradable polymers made of lactides using copolymerized lactones (see Grijpma column 1, lines 57-62, Ohara column 3, lines 8-12). In this case, Ohara is used as evidence of polymers made of lactides using copolymerized lactones that have specific properties not taught by Grijpma. Further, Ohara teaches the method for producing a polylactic acid that is biologically safe, having a high

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molecular weight of 200,000 to 500,000, and is freed from coloration and containing substantially no decomposition products (Column 1, lines 14; Column 2, lines 22-24). The presences of lactides and decomposition products cause undesirable adherence to nozzles during molding and deterioration of polymer formability and thermal stability (Column 1, lines 54-61). Ohara further teaches the polylactic acid can be further progressed and unreacted lactide can be reacted further, the reaction can be terminated to yield an average high molecular weight polymer (column 2, lines 5-7, examples 1-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the teachings of Ohara to make the high average molecular weight polylactic acid that contains substantially no decomposition products to produce Grijpma's biodegradable gum using a good quality formable polymer.

37. Applicant argues (see Remarks Page 4) that Li does not well define the molecular weights.

38. In response to applicant's argument, Li teaches several embodiments wherein the poly (D, L-lactic acid) has a molecular weight range of approximately 2000 to about 2000000 g/mol and 10000 to about 500,000 g/mol (Page 2, lines 27, 30). Although Li does not teach Mn, the fact that the range is taught, would permit one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures and selected the polymer Mn above 105,000 g/mol and still be within the range taught by Li.

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39. Applicant's arguments, see Remarks pages 7-8, filed 5/10/2010, with respect to Owusu-Anash in view of Hoseny have been fully considered and are persuasive. The rejection of claim 1-9, 14-19, 21, 28,29 and 39-41 has been withdrawn.

Double Patenting

40. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

41. Claims 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53, 56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 7,507,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims to a coated chewing gum comprising biodegradable polymers are

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considered obvious over conflicting claims to specific amounts by weight of the chewing gum center comprising an environmentally degradable chewing gum center and an outer coating.

42. Claims 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53, 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over: claims 1, 2, 4-6, 8, 10-13, and 15-66 of copending Application No. 10/528,926; claims 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-43, and 45-64 of copending Application No. 10/528,930; and claims 1, 3-7, and 9-55 of copending Application No. 10/529,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because the chewing gum claimed in the claims of each of said applications is merely an obvious variation of the chewing gum claimed by applicant in the instant application. Application 10/528,926 claims a chewing gum comprising biodegradable polymers in terms of Tg. Application 10/528,930 claims a chewing gum comprising biodegradable polymers polymerized from specific monomers. Application 10/529,137 claims a chewing gum comprising biodegradable polymers and conventional chewing gum ingredients. The copending claims to different properties of the polymers (e.g. Tg) or the specific monomers from which the polymers are produced are all considered to be obvious variations of the instant claims as one of ordinary skill would have found it obvious to alter these properties depending on the texture desired in the final chewing gum product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

44. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saeeda Latham whose telephone number is 571-270-1154. The examiner can normally be reached on Monday to Thursday 8:00AM - 5:00PM EST.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L./

Examiner, Art Unit 1782

/Rena L. Dye/

Supervisory Patent Examiner, Art Unit 1782